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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

THERANOS, INC. and ELIZABETH HOLMES, Plaintiffs, v. FUISZ PHARMA LLC, RICHARD C. FUISZ, and JOSEPH M. FUISZ, Defendants.	Case No. 11-CV-05236-YGR **REPLY IN SUPPORT OF MOTION TO STRIKE INFRINGEMENT CONTENTIONS**
FUISZ PHARMA LLC, Plaintiff, v. THERANOS, INC. Defendants.	Case No. 12-CV-3323-YGR Date: November 20, 2012 Hearing Time: 2:00 p.m.

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I. INTRODUCTION

The Patent Local Rules require that a party's infringement contentions identify every accused product for each asserted claim and where each limitation of each claim is found within each of these accused products. Patent L.R. 3-1. Armed with this information, the accused infringer then identifies and produces documents sufficient to show the operation of any aspects or elements of any of the accused products that the accusing party identified in its infringement contentions. These procedures are carefully orchestrated to "facilitate the exchange of information between parties so that discovery can proceed in an orderly fashion . . . The [Patent Local] Rules are designed to make discovery more manageable, and to reduce the likelihood that defendant will need to spend time and money defending products that were mistakenly included in plaintiff's contentions." *Bender v. Micrel Inc.*, No. 09-1144, 2010 WL 520513, at *3 (N.D. Cal. Feb. 6, 2010).

The purpose of the Patent Local Rules is thwarted where, as here, the party accusing the other of infringement ignores its obligations wholesale. In this case, Fuisz Pharma's Infringement Contentions fail to identify a single accused instrumentality capable of infringing the '612 patent, let alone provide specific information as to *how* any such accused instrumentality allegedly meets the asserted claims. Fuisz Pharma's so-called Infringement Contentions do nothing to apprise Theranos of Fuisz Pharma's theory of infringement, and so fail to meet even the most minimal requirements of the Patent Local Rules.

Ignoring these deficiencies, Fuisz Pharma's Opposition tries to blame Theranos for Fuisz Pharma's own failure to form a reasonable belief, prior to filing suit, that particular Theranos products meet each and every element of the asserted claims of the '612 patent. For instance, Fuisz Pharma complains that there is insufficient evidence in the public record regarding the completion dates of the clinical trials on which Fuisz Pharma bases its Infringement Contentions. But Fuisz Pharma fails even to address the evidence that Theranos cites in its opening brief—based upon the very same disclosures that Fuisz Pharma cites in its Infringement Contentions—showing that the trials were in fact completed *before* the '612 patent issued. And even assuming for the sake of argument that they were not, Fuisz Pharma

offers no information at all about the devices allegedly used in those trials, let alone a shred of evidence that they infringed any claim of the '612 patent.

Fuisz Pharma fundamentally misunderstands the law: the patentholder has the burden of coming forward with evidence of infringement. It is black letter law that the patentholder *must* comply with Patent Local Rule 3-1, whether or not information on accused products is publicly available. *See, e.g.*, *View Eng'g, Inc. v. Robotic Vision Sys., Inc.*, 208 F.3d 981, 985–86 (Fed. Cir. 2000) ("[The accused infringer] is not required to allow pre-litigation discovery, as requested by [the patentholder], nor is it required to allow [the patentholder] to any discovery not approved by the Court."); *Shared Memory Graphics LLC v. Apple, Inc.*, No. C-10-02475, 2011 WL 3878388, at *7 (N.D. Cal. Sept. 2, 2011) ("[The patentholder] contends that the Court should require defendants to produce discovery that would reveal whether the [] limitations are found in each accused device. . . This argument, however, . . . violates Local Rule 3-1(c).").

Where infringement contentions are deficient, courts routinely refuse to order an accused party to produce infringement-related discovery, and often halt discovery altogether. *See, e.g.*, *Bender v. Maxim Integrated Prods., Inc.*, No. C 09-1152, 2010 WL 1135762, at *2–3 (N.D. Cal. Mar. 22, 2010). Ignoring these court decisions, Fuisz Pharma nevertheless argues for discovery relating to infringement by claiming that *Theranos's* affirmative claims regarding correction of inventorship and unfair competition somehow justify discovery on that topic. Fuisz Pharma's argument makes no sense. First, Theranos has already fully complied with the Patent Local Rules as to its own affirmative claims, as evidenced by the 271-page invalidity contentions that it timely served on Defendants. Theranos has already produced documents on which it relies and will, of course, continue to participate fully in discovery reasonably related to its affirmative claims, including all elements as to which Theranos bears the burden of proof (such as damages). But more important, Fuisz Pharma's argument that it is entitled to infringement-related discovery based on Theranos's claims fails to address the significant separation in time between facts relevant to those claims and those which might conceivably be relevant to Fuisz Pharma's infringement case. Theranos's claims are based on research and prior art that *predates April 24, 2006*—the date on which Fuisz Pharma filed the patent

application that became the '612 patent. In stark contrast, the information that Fuisz Pharma alleges that it needs for its infringement claim necessarily relates to conduct *after November 2, 2010*, the date on which the '612 patent eventually issued. In short, there is more than a four and a half year gap in time, and little to no subject-matter overlap, between the discovery that the two parties seek. Fuisz Pharma's attempt to conflate the two is highly misleading.

II. ARGUMENT

A. Fuisz Pharma Has Not Presented Any Viable Excuse For Its Failure To Comply With Patent Local Rule 3-1.

Although Theranos' motion identified specific, glaring deficiencies in Fuisz Pharma's Infringement Contentions, Fuisz Pharma barely addresses most of them and ignores others entirely. The arguments Fuisz Pharma does present in the Opposition are at best unpersuasive, and more often, irrelevant.

1. Fuisz Pharma Has No Evidence That Any Accused Instrumentalities Were Made, Used, Sold, Or Offered For Sale *After* The '612 Patent Issued.

Because there is no evidence that the accused instrumentalities were made, used, sold, or offered for sale following the issuance of the '612 patent, Fuisz Pharma cannot assert infringement. *See* 35 U.S.C. § 271(a); 35 U.S.C. § 154; *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1237 (Fed. Cir. 1985). Fuisz Pharma's accused instrumentalities are devices that it describes as having been used in three different clinical trials that concluded *prior* to the issuance of the '612 patent. Fuisz Pharma's Opposition specifically admits that it relies solely on these clinical trials for its infringement allegations. (Opposition on Motion to Strike (Dkt. No. 101) ("Opp.") at 2, 5, 15.) But as described in detail in Theranos's opening brief, the very records on which Fuisz Pharma relies state that the three clinical trials—the Stanford Trial, the Mayo Clinic Trial, and the GlaxoSmithKline Trial—concluded prior to November 2, 2010, when the '612 patent issued. (See Nousek Decl. Exs. C–E (Dkt. Nos. 99-5, 99-6, 99-7).) [1]

[1] For example, Fuisz Pharma's evidence of the GlaxoSmithKline trial states that the study was completed as of March 2010. (Nousek Decl. Ex. C at FUISZ000309 (Dkt. No. 99-5).) Likewise, the evidence Fuisz Pharma cites regarding the Stanford Trial shows that it was

Incredibly, Fuisz Pharma admits that "there is no evidence that Theranos technology has changed since these studies," and criticizes Theranos for not "proving" that the trials were completed prior to the issuance of the '612 patent. (Opp. at 5, 16.) But Fuisz Pharma ignores that it has the burden of proof on infringement, not Theranos. *Bender v. Maxim Integrated Products, Inc.*, No. C 09-1152, 2010 WL 2991257, at *3 (N.D. Cal. July 29, 2010) ("Plaintiff may not shift the burden of identifying his claims to [the defendant] in this manner."). The *absence* of evidence as to whether Theranos has changed its technology since the clinical trials in no way supports an infringement claim. This is particularly true where Fuisz Pharma has presented *no evidence in the first instance* (in its Infringement Contentions or its Opposition) that the accused instrumentalities in fact practiced any claim of the '612 patent, even assuming for the sake of argument that they had been made, used, sold, or offered for sale after the '612 patent issued. Because Fuisz Pharma has not identified a single accused device that could have infringed the '612 patent, it has failed to satisfy Patent Local Rule 3-1.

Fuisz Pharma also argues that Theranos should be forced to produce information and documents regarding its products and clinical trials in existence prior the issue date of the '612 patent because this information might somehow show that post-issuance products infringe the '612 patent. (Opp. at 15–16.) In support, Fuisz Pharma points to the statement in *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 303 (Fed. Cir. 1995), where the Federal Circuit suggested that pre-issuance engineering drawings and templates used to build accused products sold *after* the patent issued could be relied on to prove infringement. (Opp. at 15–16.) As an initial matter, *Hoover* predates the Patent Local Rules by several years, and has nothing to do with Fuisz Pharma's obligations in the trial court. More important, and unlike the patentholder in *Hoover*, Fuisz Pharma's argument ignores that its Infringement Contentions do not identify a single post-issuance Theranos product. Fuisz Pharma has not offered—and

completed as of May 2009, (Nousek Decl. Ex. D at FUISZ000314), and the evidence Fuisz Pharma cites regarding the Mayo Clinic Trial shows that it ended in September 2010. (Nousek Ex. E at 2.) Fuisz Pharma ignores these dates and points instead to the dates on which the summary write-ups were last updated. (Opp. at 16.) Those dates, however, are irrelevant to when any of the accused instrumentalities were used.

cannot offer—any evidence whatsoever that Theranos made, used, sold, or offered for sale any allegedly infringing products *after* the '612 patent issued. And Fuisz Pharma cites no cases in which a court has allowed discovery to proceed on pre-issuance products because an accusing party hypothetically could learn information that might support an infringement argument.

2. Fuisz Pharma Does Not Dispute That It Has Admitted That The Allegedly-Infringing Conduct Identified In Its Complaint and Counterclaim Is Prior Art to the '612 Patent.

As detailed in Theranos's opening brief, Fuisz Pharma's infringement claim and counterclaim rely solely on a description of allegedly infringing conduct that Fuisz Pharma admits is prior art to the '612 patent. Indeed, the description is lifted verbatim from the "Technical Field" section of the '612 patent. (Case No. 12-cv-03323-YGR, Dkt. No. 1, Ex. A at col. 1:49–2:7; Case No. 11-cv-05236-YGR, Dkt. No. 84, Ex. F at col. 1:49–2:7.) A patent applicant's statement in a patent or during prosecution that the work of another is prior art is a binding legal admission in subsequent disputes regarding anticipation or obviousness. *Riverwood Int'l Corp. v. R.A. Jones & Co*., 324 F.3d 1346, 1354 (Fed. Cir. 2003) ("Valid prior art may be created by the admissions of the parties."); *see also Constant v. Advanced Micro-Devices, Inc*., 848 F.2d 1560, 1569–70 (Fed. Cir. 1988) (holding applicant bound by concessions in specification section of patent that everything described in the patent was prior art technology except the use of RAMs). Because the sole allegedly infringing conduct that Fuisz Pharma has identified *outside* of its deficient Infringement Contentions is admitted prior art to the '612 patent, it is axiomatic that that conduct cannot infringe the '612 patent either. *See, e.g., Tokyo Keiso Co., Ltd. v. SMC Corp*., 307 Fed. App'x 446, 451 (Fed. Cir. 2009).

Fuisz Pharma does not dispute its prior admission that Theranos's allegedly infringing conduct is prior art. Instead, it argues (somewhat ironically) that Theranos "mischaracterizes and misuses the term prior art," further stating that Theranos's argument "goes not to the sufficiency of Fuisz Pharma's Infringement Contentions . . . but to the entirely separate issue of *invalidity*." (Opp. at 15 (emphasis in original).) Fuisz Pharma is confused. Its reliance in its complaint and counterclaim on allegedly infringing conduct that it had previously admitted is

prior art to the '612 patent simply demonstrates that Fuisz Pharma has no basis for its infringement claims against Theranos.[2]

3. A Lack Of Publicly-Available Information On Theranos' Devices Does Not Excuse Fuisz Pharma's Failure To Comply With Patent Local Rule 3-1.

Fuisz Pharma's Infringement Contentions also fail to provide "[a] chart identifying specifically where each limitation of each asserted claim is found within each Accused Instrumentality." As Theranos describes in its opening brief, the Patent Local Rule 3-1(c) chart that Fuisz Pharma provides as part of its Infringement Contentions is absurdly deficient. (Theranos Mot. at 11–14.) Among other things, it impermissibly ignores certain asserted claims, and many of the identified aspects of the alleged product have no logical relationship to the claim element cited. And for most limitations, Fuisz Pharma simply recites, "on information and belief," that the Theranos devices allegedly practice the limitation. Fuisz Pharma's Local Rule 3-1(c) chart is facially inadequate, and its infringement contentions should therefore be stricken. *See Shared Memory Graphics*, 2011 WL 3878388, at *6 ("Instead, SMG simply recites the claim language and baldly asserts that the data distribution bus is satisfied. This it cannot do."); *Network Caching Tech., LLC v. Novell, Inc.*, No. C–01–2079–VRW, 2002 WL 32126128, at *5–6 (N.D. Cal. Aug. 13, 2002) (holding that infringement contentions which simply mimic claims in the patent, or are vague discussions of the claim terms, are inadequate).

Fuisz Pharma seeks to excuse its noncompliance with Patent Local Rule 3-1 on the grounds that that there is a "limited amount of information publicly available about Theranos' products." (Opp. at 12–13.) Courts in this district and elsewhere have specifically rejected this argument. *See Bender*, 2010 WL 520513, at *2–3 ("Plaintiff argues that he cannot be more specific without obtaining defendant's detailed schematics, but the Court will not permit

[2] In addition, Fuisz Pharma inexplicably points out that the clinical trials are not themselves prior art. (Opp. at 15.) But Theranos does not argue that they are prior art. As discussed above, the relevant fact is that because the trials *concluded* prior to the issuance of the '612 patent, the use of devices during those trials cannot infringe the '612 patent.

plaintiff to proceed at this point in the absence of claim charts containing more substantive infringement contentions."); *Shared Memory Graphics*, 2011 WL 3878388, at *7; *McKesson Info. Solutions LLC v. Epic Sys. Corp.*, 242 F.R.D. 689, 694–95 (N.D. Ga. 2007) (granting defendant's motion to compel amended infringement contentions, despite plaintiff's argument that it could not identify each and every element of the patent-in-suit in the accused product without discovery as to how the product works because the product is secret).

Fuisz Pharma is unable to point to any support for its remarkable argument that a patentholder is allowed to ignore the Patent Local Rules it asserts that discovery could possibly provide evidence of the existence of infringing products. Indeed, any such holding would obviate the Patent Local Rules entirely, by improperly shifting to the accused party the burden of establishing through discovery whether its devices practice the limitations at issue. This Court has expressly rejected that argument:

> Finally, [the plaintiff] contends that the Court should require defendants to produce discovery that would reveal whether the data distribution bus limitations are found in each accused device. [The plaintiff's] theory is that since Defendants know what is in their devices, the Court should just make them show their hand. This argument, however, as does [the plaintiff's] others, violates Local Rule 3–1(c). . . . There is simply no support, in the case law or otherwise, for [plaintiff's] request that it be excused from complying with Local Rule 3–1(c) for certain limitations, and that instead Defendants bear the burden of establishing through discovery whether their devices practice the limitations at issue.

Shared Memory Graphics, 2011 WL 3878388, at *7.

Pursuant to Rule 11, Fuisz Pharma was required to have a reasonable belief, *prior to filing suit*, that particular Theranos products meet each and every element of the asserted claims of the '612 patent. *McKesson*, 242 F.R.D. at 694–95 (rejecting proposition that secrecy of information excused insufficient infringement contentions, citing *View Engineering*). The Federal Circuit held in *View Engineering, Inc. v. Robotic Vision Systems, Inc.*, that Rule 11 requires that a plaintiff be able to demonstrate "exactly why it believed *before filing the claim* that it had a reasonable chance of proving infringement." 208 F.3d at 986 (emphasis added) ("A patent suit can be an expensive proposition. Defending against baseless claims of infringement subjects the alleged infringer to undue costs—precisely the scenario Rule 11

contemplates."). In *View Engineering, Inc.*, the Federal Circuit specifically rejected the sanctioned party's argument that it could not have determined prior to filing its infringement counterclaim whether the accused products infringed because it had not been permitted to examine the allegedly infringing products or drawings of the products. *Id.* at 985–86. Accordingly, Fuisz Pharma cannot be permitted to file suit in which a reasonable belief of infringement is required under Rule 11 and then, as it does here, claim that information that could form the basis of a reasonable belief is available only through discovery. *See id.*

Fuisz Pharma cites *DCG Systems v. Checkpoint Technologies, LLC*, No. C 11-03792, 2012 WL 1309161 (N.D. Cal. Apr. 16, 2012), but this opinion does not even remotely assist it. The court there ruled only that the plaintiff could *amend* its infringement contentions—which were already legally sufficient—to add *additional asserted claims* against the *already accused products*. The decision has nothing to do with our case, where Fuisz Pharma has not complied with Patent Local Rule 3-1 as to even a single product.

Fuisz Pharma's reliance on *American Video Graphics, L.P. v. Electronic Arts, Inc.*, 359 F. Supp. 2d 558 (E.D. Tex. 2005), is similarly misplaced. As an initial matter, *American Video Graphics* is flatly inconsistent with the decisions from this district and elsewhere. *See Shared Memory Graphics*, 2011 WL 3878388, at *7; *Infineon Technologies v. Volterra Semiconductor*, No. C-11-06239-MMC, 2012 WL 1998440, at *2 (N.D. Cal. June 4, 2012); *View Eng'g*, 208 F.3d at 986; *see also McKesson*, 242 F.R.D. at 694–95. Furthermore, the relevant issue in that case was whether the plaintiff had provided sufficient detail in its infringement contention to map the claim elements to the accused products. *American Video Graphics*, 359 F. Supp. 2d at 560–61. But here, Fuisz Pharma's deficiency is much more fundamental: Fuisz Pharma has failed to identify *any* potentially infringing accused instrumentalities.

Fuisz Pharma's excuses have been squarely rejected by courts in this district and elsewhere. Its Infringement Contentions should be stricken for the failure to comply with Patent Local Rule 3-1.

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4. Theranos Has Not Admitted That It Infringes Any Aspect Of The '612 Patent.

Fuisz Pharma falsely claims that Theranos has admitted that it infringes the '612 patent because Theranos intends to prove that its employees conceived of and invented subject matter claimed in the '612 patent. (Opp. at 9–12.) Fuisz Pharma's argument is bizarre.

Fuisz Pharma's assertion demonstrates a fundamental misunderstanding of the difference between conceiving an invention and practicing it after someone else has patented it. In this case, Theranos will prove that it was the first to conceive certain claimed subject matter in the '612 patent, as evidenced by numerous documents, including provisional patent applications and other confidential information to which Fuisz Pharma had improper access. But Theranos has never claimed that it made, used, sold, or offered for sale any device that practices the '612 patent, before or after the issue date of the patent. And Fuisz Pharma has cited no such evidence. (Opp. at 9–12.) The fact that Theranos has conceived an invention, disclosed it in patent filings, or owns related patents, does not mean—or even suggest—that it has ever practiced the inventions described in those documents, let alone done so after the issue date of the '612 patent. *See, e.g., Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995) ("There is no requirement in this country that a patentee make, use, or sell its patented invention.") (internal citations omitted); *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 703–04 (Fed. Cir. 2008) (acknowledging that the patentee "does not currently practice [its own] claimed inventions").

Fuisz Pharma's purported support for this line of argument in the Opposition is a claim chart that Fuisz Pharma has disingenuously titled "Admissions." The so-called "admissions" in this chart are actually nothing more than excerpts from Theranos' Invalidity Contentions, which in turn cite to Theranos's own prior art. (Opp. at 10–12.) Even ignoring, for the sake of argument, the critical distinction identified above between invention disclosures and actual practice thereof, the relevant dates for all of the prior art on which Theranos relies in its Invalidity Contentions also predate the date of issuance and enforceability of the '612 patent by more than four years. (*See* Declaration of Lisa Nousek In Support of Reply ("Nousek Reply

Decl."), Ex. A.) Under no circumstances can Theranos's invalidity contentions be an admission regarding infringement.

Fuisz Pharma also spends several pages of its Opposition on an incoherent argument regarding estoppel. As we understand it, Fuisz Pharma appears to be saying that Theranos should be precluded from pursuing its non-infringement arguments, or from seeking to strike Fuisz Pharma's Infringement Contentions, because it allegedly admitted infringement in its Amended Complaint and Infringement Contentions. (Opp. at 16–18.) For the reasons discussed above, there is no such admission or estoppel.

Although confusing, Fuisz Pharma also appears to suggest that Theranos admitted infringement by "abandon[ing]" an interference proceeding at the Patent Office. Fuisz Pharma fundamentally misunderstands the facts and the law. First, because the Patent Office never declared an interference, there was no interference proceeding that could be abandoned. Second, even if an interference proceeding were declared, the purpose of such an action is to have the Patent Office determine claims of *inventorship*, not infringement. *See Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998) ("When a patent application is filed which would interfere with any pending application or with any unexpired patent, the Commissioner of the PTO is authorized to declare an interference to determine which party was the first to invent the claimed subject matter."); *Muller v. Olin Mathieson Chem. Corp.*, 240 F. Supp. 662, 664 (S.D.N.Y. 1965) ("[T]he purpose of an interference proceeding, . . . is to determine which of the parties who may rightfully make the common claim is the first inventor."). Third, before Theranos abandoned the patent application (not interference proceeding) to which Fuisz Pharma refers, it filed another continuation application with claims that were also copied from the '612 patent. At least one continuation application is still pending with similar claims and provides a vehicle for the Patent Office to declare an interference if it should deem such a proceeding appropriate in the future. Fourth, even if a party hypothetically were to "abandon" an interference proceeding, there could be no estoppel with regard to inventorship, much less infringement. 35 U.S.C. § 256 expressly provides an independent remedy for a federal court litigant to correct inventorship of an issued patent, and

as noted above, interference and infringement are conceptually unrelated. In short, Fuisz Pharma fails to support its novel estoppel theory.

B. Numerous Courts Have Stayed Discovery Where An Accusing Party's Infringement Contentions Were Deficient.

Multiple courts in this district have stayed discovery as a result of deficient infringement contentions. *See, e.g., Shared Memory Graphics LLC v. Apple, Inc.*, 812 F. Supp. 2d 1022, 1026–27 (N.D. Cal. 2010) (staying discovery where the court found that the plaintiff's initial Infringement Contentions were deficient because they included vague contentions and conclusory statements that did not provide fair notice as to what components and circuitry of the accused products infringed the plaintiff's patents); *Shared Memory Graphics*, 2011 WL 3878388, at *8 (ordering the stay of discovery to remain in effect where the plaintiff's amended infringement contentions continued to be deficient); *Network Caching*, 2002 WL 32126128, at *7 (staying discovery pending the plaintiff serving revised infringement contentions); *Bender*, 2010 WL 1135762, at *2; *Bender*, 2010 WL 520513, at *3; *Bender*, 2010 WL 2991257, at *5–6.

Rather than address any of these cases, Fuisz Pharma argues that infringement-related discovery should not be stayed because: (1) Theranos initiated this lawsuit; (2) Theranos has asserted claims against Fuisz Pharma for correction of inventorship and unfair competition, and has sought damages for these claims; and (3) Theranos allegedly has no evidence to support its claims. Even assuming for the sake of argument that these unsupported statements were true, none excuse Fuisz Pharma's deficient Infringement Contentions or suggest that infringement-related discovery should nevertheless proceed.

First, Theranos's initiating this lawsuit is wholly irrelevant to whether infringement-related discovery should be allowed to proceed. Fuisz Pharma affirmatively asserts an infringement claim against Theranos, based on the '612 patent.[3] It is this claim, not Theranos's

[3] Indeed, Fuisz Pharma originally filed its claim as an independent lawsuit in Delaware when no action against it was pending there. Over its objection, the Delaware court transferred the case to this Court.

separate claims, that triggers the obligations under Patent Local Rule 3.1 that Fuisz Pharma has failed to fulfill, and for which Theranos seeks a stay.

Second, infringement-related discovery is irrelevant to Theranos' claims for correction of inventorship or unfair competition. The question of who conceived the inventions of the '612 patent necessarily involves conduct that occurred *prior* to the filing of the application of the '612 patent in 2006. Infringement-related information, on the other hand, relates to conduct that took place *after* the '612 patent issued many years later. Theranos is producing responsive information and documents relevant to inventorship issues. Documents concerning Theranos products after the date the '612 patent issued are irrelevant to this issue. Likewise, Theranos's post-issuance conduct is equally irrelevant to its unfair competition claim. The unfair competition claim flows directly from Fuisz Pharma misappropriating Theranos's invention of the '612 patent. Again, the focus of this claim is on conduct that took place *prior* to the filing of the application of the '612 patent in 2006.

As to damages, Theranos is producing responsive documents that are relevant to damages arising under its inventorship and unfair-competition claims. To the extent that these damages-related documents may also relate to Fuisz Pharma's infringement claims, Theranos does not contend that it should be excused from producing them. Rather, due to Fuisz Pharma's deficient Infringement Contentions, Theranos argues only that it should not now be required to produce documents that relate solely to Fuisz Pharma's unsubstantiated infringement claim.

Relatedly, Fuisz Pharma puts much misdirected emphasis on the argument that infringement-related discovery is necessary because Theranos pleaded in the Second Amended Complaint that its ability to enjoy the '612 Patent "and inventions based thereon" has been harmed by Fuisz Pharma's actions. (Opp. at 3, 7.) But this statement is far from an admission that Theranos is currently making—or has ever made—any "inventions based" on the '612 patent. Quite the opposite: Theranos claims it has been damaged by its inability to make "inventions" that practice the '612 patent because Fuisz Pharma misappropriated Theranos's ideas. In short, this statement communicates nothing about Theranos's practice of the '612 (or

lack thereof), but rather complains that Theranos has lost its rightful ability to do so.

In summary, Theranos's Invalidity Contentions overwhelmingly demonstrate that its affirmative claims are well-founded. But in any event, the presence or absence of evidence in support of Theranos's claims has no bearing on Fuisz Pharma's own compliance with the Patent Local Rules and the consequences that flow from its failure to meet those obligations. In light of the fundamental failures in Fuisz Pharma's Infringement Contentions, Theranos should not be forced to bear the costs of infringement-related discovery.

III. CONCLUSION

For the reasons stated above and in Theranos' opening brief, the Court should strike Fuisz Pharma's Infringement Contentions and stay discovery relating to infringement.

Dated: November 2, 2012

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